(CD)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/009,627 | 10/26/2001 | Isamu Uemasu | 100745-7 / Miura 214-KGB | 3737 |

7590 06/29/2004

Norris McLaughin & Marcus
220 East 42nd Street 30th Floor
New York, NY 10017

| EXAMINER | |
|---|---|
| KHARE, DEVESH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/009,627 | UEMASU ET AL. | |
| | Examiner | Art Unit | |
| | Devesh Khare | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-5 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The response and amendment filed on 1/22/2004 are acknowledged. Claim 8 has been amended. It is noted that on page 3 of the issued office action dated 09/17/2003, the recited U.S. Patent is corrected to U.S. Patent No. 5,177,302 (Uemasu et al.). Claims 3-5 and 8 are currently pending in this application.

***35 U.S.C. 112, second paragraph rejection***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 3-5 and 8 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 8 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

## ***35 U.S.C. 103(a) rejection***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

**Claims 3-5 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Uemasu et al. (U.S.Patent 5,177,302) in view of Armstrong et al. (Anal. Chem., 59,2237-2241,1987) of record.

Claims 3-5 and 8 are drawn to a continuous and selective inclusion separation method having at least two liquid-liquid interfaces between an organic phase containing a compound to be separated and an aqueous solution of inclusion-complexing agent. The respective liquid-liquid interfaces are stirred to entrap at least one compound to be separated into said aqueous phase through formation of at least one inclusion complex of said inclusion-complexing agent and dissociation of said inclusion complex wherein a diaphragm permeable to said aqueous solution of inclusion complexing agent but hardly permeable to organic phases is provided.

The claim limitations include the inclusion-complexing agent cyclodextrin, the compound for separation is a raw material selected from the group consisting of indole containing mixtures or a di- and tri- substituted benzene isomer mixtures and the organic phase

containing a compound is separated by distillation of the concentrate and returned back to the reaction system.

Uemasu et al. (5,177,302) teach a process for separating isomers of disubstituted benzenes using cyclodextrins as an inclusion-complexing agent (abstract). Uemasu et al. disclose that the cyclodextrin is used as an agent for separating isomers of benzene compounds (col. 1, lines 38-40). Uemasu et al disclose the separation of xylene isomers wherein the organic phase containing xylene is stirred or shaken with the substituted cyclodextrin dissolved in water then the aqueous layer is separated from oil layer (col. 3, lines 10-24) and extracted benzene isomers can be recovered from the organic layer by evaporating the organic solvent (col. 3, lines 37-39). Uemasu et al differ from the applicant's invention in that Uemasu et al. do not disclose the use of diaphragm or membrane in the separation process.

Armstrong et al. teach the isomeric separation of enantiomers and isomers through aqueous-cyclodextrin based liquid membranes (abstract). Armstrong et al disclose that membrane based separations can be used in continuous processes (page 2237, 2nd col., 2nd para.). Armstrong et al. disclose that the cyclodextrin inclusion complex of a isomer at the aqueous-organic interface is diffused across the membrane and the isomer is released at the opposite end (page 2238, 2nd col., "Results and Discussion" lines 5-10). Armstrong et al. also disclose the membrane separation conditions for benzene-substituted compounds in Table 1, page 2239.

Therefore, one of ordinary skill in the art would have found the applicants claimed continuous and selective inclusion separation method having at least two liquid-liquid interfaces between an organic phase containing a compound to be separated and an aqueous solution of inclusion-complexing agent(cyclodextrin) with the use of diaphragm or membrane, to have been obvious at the time the invention was made having the above-cited references before him. Since Uemasu et al. teach a process for separating isomers of disubstituted benzenes using cyclodextrins as an inclusion-complexing agent and Armstrong et al. teach the isomeric separation of enantiomers and isomers through aqueous-cyclodextrin based liquid membranes, one skilled in the art would have a reasonable expectation for success in combining both references to provide continuous and selective inclusion separation method by utilizing at least two liquid-liquid interfaces between an organic phase containing a compound to be separated and an aqueous solution of inclusion-complexing agent (cyclodextrin). The motivation for doing so is provided by Uemasu et al's patent, which discloses an economical process for separating a xylene isomer by utilizing a substituted α-cyclodextrin, with the aim of improving the water solubility of α-cyclodextrin (col.1, lines 66-68 to col. 2, lines 1-2).

***Rejection Maintained***

Rejection of claims 3-5 and 8 under 35 U.S.C. 103(a) is maintained for the reasons of record.

***Response to Arguments***

Applicant's arguments traversing the rejection of claims 3-5 and 8 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Applicants argue, "there is absolutely nothing in the prior Uemasu reference or in its combination with Armstrong that teaches or suggests these results". Applicant's invention is toward a separation method wherein a partitioning diaphragm is provided, or disposed, which is used to permeate the aqueous solution of inclusion-complexing agent but substantially impermeable to oil droplets of the organic phases. Uemasu et al. disclose that the cyclodextrin is used as an agent for separating isomers of benzene compounds (col. 1, lines 38-40). Uemasu et al differ from the applicant's invention in that Uemasu et al. do not disclose the use of diaphragm or membrane in the separation process. Armstrong et al. teach the isomeric separation of enantiomers and isomers through aqueous-cyclodextrin based liquid membranes (abstract). Armstrong et al. disclose that "some structural isomers selectively permeate a bulk aqueous membrane largely because of the differential solubilities and pKa of these isomers in water" (page 2239, first col., lines 1-3), however the permeability of the cyclodextrin-complexed molecules are greatly enhanced through the said membranes (page 2239, first col., lines 4-8).

Indeed, the examiner has established a prima facie case of obviousness rendering claims 1-14 rejected under 35 U.S.C. 103(a) by addressing sufficiently all of the limitations set forth in the instant process for a separation method wherein a partitioning diaphragm is provided, or disposed, which is used to permeate the aqueous solution of inclusion-complexing agent but substantially impermeable to oil droplets of the organic phases, one skilled in the art would have a reasonable expectation for success in

combining the teachings of Uemasu et al. and Armstrong et al. references to accomplish the claimed separation method wherein a partitioning diaphragm is provided, or disposed, which is used to permeate the aqueous solution of inclusion-complexing agent but substantially impermeable to oil droplets of the organic phases.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
June 24,2004